

23. The method according to any one of claims 7 and 17-19 wherein the formoterol is in the form of the fumarate dihydrate.--

REMARKS

Claims 1-3 and 5-13 are pending in the application. Claims 1, 2 and 7 have been amended. Claims 3, 5, 6 and 8-13 have been withdrawn from further consideration in this application. New claims 14-23 have been added.

The title has been amended, and a number of amendments to the specification have been made to correct typographical errors. No new matter has been introduced by any of the changes.

Claims 1, 2 and 7 have been amended to better define the subject matter regarded as the invention. In particular, claim 7 has been amended so that it is directed to treatment of asthma and other inflammatory respiratory disorders. New claims 14-23 have been added to more particularly recite preferred embodiments of the invention.

Claim 14 is directed to a particular embodiment of the inventive combination, namely, the active agents in dry powder form. Support for claim 14 can be found on page 6, lines 31-36 and Example 1 of the specification.

Claims 15, 16 and 23 recite a preferred form of the formoterol component of the combination. Support for these claims can be found on page 6, lines 14 and 15 of the specification.

Claims 17-19 recite preferred amounts and ratios of the two active ingredients. Support for these claims can be found on page 6, lines 17-29 of the specification.

Claims 20-22 are directed to particular means of administering the inventive combinations. Support for these claims can be found on page 6, lines 31-36 of the specification. No new matter has been introduced by any of the amendments to the claims.

Applicants acknowledge with gratitude the interview with Examiner Henley on August 17, 1994 in the parent application. Applicants appreciate the time and consideration the Examiner gave this matter at that time and continued to give subsequent to the interview.

As part of the follow-up to the Examiner interview, Applicants' agent sent to the Examiner by facsimile on September 12, 1994 a draft of a Declaration under 37 CFR § 1.132 setting forth data in support of the nonobviousness of the claimed formoterol-budesonide combinations. In subsequent telephone discussions (September 14 and September 21, 1994), the Examiner indicated that he found the presented data supportive of

nonobviousness but insufficient to enable the scope of the invention as presently claimed. The Examiner further indicated that the Declaration was lacking in that it contained no statement to the effect that the tests performed are predictive of efficacy of the test compounds in the treatment of any respiratory disorder. Accordingly, in the outstanding office action the Examiner has maintained the prior rejections of the claims under 35 U.S.C. §103 for the reasons of record.

Applicants will submit within two weeks for the Examiner's consideration a formal Declaration under 37 CFR § 1.132 by Dr. Jan Trofast, a coinventor of the instant application and a participant in the August 17, 1994 interview. The Declaration sets forth the data submitted on September 12, 1994, as well as extensive additional data demonstrating the unexpected efficacy of the claimed formoterol-budesonide combinations in a range of dosages. The Declaration also includes exhibits, including published references corroborating the validity of the tests performed in demonstrating efficacy of test compounds for the treatment of asthma and other inflammatory respiratory disorders. The data set forth in the Declaration serve to overcome the Examiner's rejection of the claims under 35 U.S.C. § 103 as obvious over Brattsand, et al. and Murakami, et al. The material set forth in the Declaration

further provides sufficient enablement for the scope of the invention as claimed, both in terms of absolute amounts and relative amounts (ratios) of active ingredients as well as utility, and thus overcomes the grounds for rejection of the application set forth in the September 19, 1994 Examiner Interview Summary Record.

Enclosed with this communication for the Examiner's information are copies of two published articles, one by Salonen, Acta Pharmacologica et Toxicologica 57, 1-33 (1985) and the other by Svedmyr, Am. Rev. Respir. Dis. 141, S31-S38 (1990). These articles provide further insight into the state of the relevant art and further support for the contention that the teachings in the art would not lead one to the instantly claimed compositions and methods of treatment.

Based on the above, it is submitted that the claims are directed to patentable subject matter and in condition for allowance. Reconsideration and allowance of pending claims 1, 2, 7 and 14-23 are respectfully requested. Should any other matters require attention prior to allowance of the application, it is requested that the undersigned be contacted.

The Assistant Commissioner is hereby authorized to charge any fees due in connection with this communication to Deposit Account No. 23-1703.

Dated: May 23, 1995

Respectfully submitted,



Richard J. Sterner
Reg. No. 35,372

White & Case
1155 Avenue of the Americas
New York, New York 10036
(212) 819-8783

Enclosures